DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Light Med Corporation
c/o Mr. Thomas V. Keeley
110 Via Estrada, Suite P
Laguna Woods, California 92653

Re: K010372
Trade/Device Name: LightLas 532 Ophthalmic Photocoagulator Laser
Regulation Number: 886.4390
Regulatory Class: II
Product Code: HQF
Dated: May 30, 2001
Received: May 30, 2001

Dear Mr. Keeley:

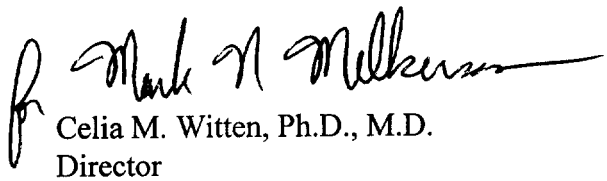
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

510(k) Number (if known): K010372

Device Name: **LightLas 532 Ophthalmic Photocoagulator Laser**

Indications For Use:

The Indications for use of this device are to perform:

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Laser Trabeculoplasty
- Macular Treatments
- Endophotocoagulation

The LightLas 532 Laser beam has a wavelength of 532nm, which is in the visible spectrum and is a green light. A red aiming beam is used to position the treatment Green beam prior to delivery.

The Retinal treatments, including retinal and pan retinal photocoagulation and endophotocoagulation, are treatments that involve the destruction of neovascular complexes, to destroy areas of microinfarction or capillary closure.

The Retinal photocoagulation treatment will be performed using the Slitlamp Delivery unit and the Pan retinal photocoagulation can be performed using either the LIO or the Slitlamp Delivery units. Endophotocoagulation is performed using the Endoprobes in a sterile environment.

Laser Trabeculoplasty is the photocoagulation of the trabecular meshwork to create apertures and thereby increase the flow of the aqueous humor in order to treat open-angle glaucoma. This treatment is performed using the Slitlamp Delivery unit

Macular treatments involve the destruction of leaking vessels in the macular and paramacular regions in order to produce a chorioretinal adhesion that can resist ongoing vitreoretinal traction. This treatment is performed using the Slitlamp Delivery unit.

(PLEASE NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010372

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)